Food Service Sanitation Regulatory Minimum Program Requirements Guidance Manual

FY 2003

Effective October 1, 2002

Food and Dairy Division
Food Service Sanitation Section

Food Service Sanitation Regulatory Minimum Program Requirements Guidance Manual

Introduction

MPRs

The minimum program requirements (MPRs) are the requirements prescribed for a local health department (LHD) food service regulatory program. Each MPR is directly derived from a requirement in statute.

Indicators

The "indicators" specify in more detail what MDA looks for as an indicator of compliance with the applicable MPR. Indicators are written as decimal subparagraphs of the applicable MPR number. For example, under MPR 1 are indicators 1.1, 1.2, and 1.3. All Indicators are directly derived from the Food Law of 2000 (FL2000).

Important Factors

Important Factors are <u>not</u> part of the MPRs. While important, they are <u>not</u> required for accreditation. Some Important Factors are directly from the law, and, while required by law, deficiencies in these areas are not considered sufficient to result in loss of accreditation status. Other Important Factors are included to advise local health departments prospectively of components essential for a program to meet requirements of the law.

Official Comments

One of the features of this document consists of the official comments prepared by the MDA food service sanitation section with advice from LHDs. These comments explain the purpose and intent of the sections. Official Comments also explain how MDA will review LHDs for compliance with the MPRs.

Program self-assessment

We strongly recommend the local health departments apply self-assessment to ensure these MPRs are being met. Effective self-assessment is essential. Experience shows that programs with ongoing and effective self-assessment are most likely to meet the MPRs. Therefore, we recommend local health departments conduct a self-assessment of their food service sanitation program every year and incorporate self-assessment components into ongoing management practices.

Minimum Program Requirements

Food Service Sanitation Regulatory Minimum Program Requirements (MPRs)

(Effective October 1, 2002)

The "official comments" are put in for clarification and explain the intent and purpose of the sections. They are not part of the minimum program requirements.

MPR 1 A local health department, upon receipt of plans and specifications for construction, alteration, conversion, or remodeling of a food service establishment, shall review the plans and specifications to determine conformance with applicable requirements. [The Food Law of 2000 (FL2000) §§ 6101 to 6113.]

- 1.1 All licensed establishments that have been constructed, altered, converted, or remodeled have submitted plans and specifications to the local health department for review. [FL2000 § 6101 and Food Code (FC) § 8-201.11.]
- 1.2 All plans and specifications submitted as required have been reviewed and, if in compliance, approved by the local health department (LHD). [FL2000 § 6107.]
- 1.3 All plans approved by the LHD comply with the law. [FL2000 $\S\S 6101$ to 6113; FC $\S\S 8-201.12$ and 8-203.10.]
- 1.4 The local health department maintains a set of plans and specifications containing the information required by the Food Law of 2000 § 6107 and Food Code § 8-201.12.

Official Comment:

- 1. MDA assesses compliance with Indicators 1.1 through 1.3 by examination of a representative sample of files.
- 2. Documentation needed to demonstrate compliance with MPR 1 includes a logbook or equivalent that shows that complete plans reviews are conducted.

MPR 2 The local health department shall conduct one or more pre-operational inspections to verify that the food establishment is constructed and equipped in accordance with the approved plans and approved modifications of those plans and is in compliance with the law. [FL2000 § 6115; FC § 8-203.10.]

- All licensed establishments have been inspected upon completion of the construction, alteration, conversion, or remodeling, and prior to opening. [FL2000 § 6115; FC § 8-203.10.]
- 2.2 When a food service establishments has undergone construction, alteration, conversion or remodeling, all construction, alteration, conversion, or remodeling approved by the LHD complies with the law. [FL2000 § 6115(2).]

- 1. MDA assesses compliance with Indicator 2.1 by examination of an MDA-selected sample of files.
- 2. MDA assesses compliance with Indicator 2.2 by a field evaluation of an MDA-selected sample of food service establishments that have undergone construction, alteration, conversion, or remodeling.

- MPR 3 The local health department shall perform an inspection of each food service establishment at least once every 6 months, except that a food service establishments which operates 9 or fewer months each year shall be inspected at least once during the period of operation by the local health department. [FL2000 § 3123.]
 - 3.1 The required quantity of inspections of licensed establishments has been completed. [FL2000 § 3123.]
 - 3.2 Inspections have been completed at the required calendar frequency. [FL2000 § 3123.]

- 1. Indicator 3.1 assesses the total number of inspections completed. The quantity of inspections required to be completed is determined by multiplying the required frequency of inspection by the establishment count. That is, seasonal establishments operating 9 months or less a year shall be inspected once per year; other food service establishment shall be inspected twice a year. Thus, if a LHD has 10 seasonal food establishments and 100 other food service establishments, then 210 inspections shall be completed over one year.
- 2. On evaluations, MDA will debit a LHD for indicator 3.1 if less than 85% of the required quantity of inspections have been completed. In calculating this percentage, the numerator is the total number of inspections completed. The denominator is the total number of inspections required to have been completed. If a reduced frequency of inspection program is in use, but is not being carried out in accordance with an approved plan, the reduction of inspections will not be subtracted from the total number of required inspections (see Indicator 9.8.) Reinspections are not counted as inspections.
- 3. Indicator 3.2 assesses whether inspections are completed within the required six-month calendar frequency. On evaluations, MDA will debit a LHD for indicator 3.2 if more than 10% of the inspections are completed more than one month late. Thus, MDA's evaluation provides a 1-month grace period for all inspections, and allows 10% of the inspections to be late by more than 1 month this permits scheduling flexibility, but does not reduce the total number of inspections required.
- 4. Indicator 3.2 is verified by review of an MDA-selected sample of files. Example: in HD's files of 16 non-seasonal food service establishments that have operated for the past 3 years, there are records of 91 inspections, and 5 of these were completed more than 7 months after the previous inspection. MDA would debit HD for Indicator 3.2 because 10 of the required inspections were completed more than 1 month beyond the required inspection date. Note: there should be records of 96 inspections (16 establishments * 2 inspections per year * 3 years = 96). Required inspections that were never completed are counted as being more than 1 month beyond the required inspection date.
- 5. An inspection must be documented on the official inspection report form or it is not counted as an official inspection.
- 6. When the law or LHD policy require normal inspection frequency for an establishment, then inspection frequency will be evaluated under normal inspection frequency. Inappropriate or incorrect programming of an establishment as reduced frequency cannot reduce the number of inspections required.
- **MPR 4** The local health department shall make compliance inspections of each vending machine location at least once every 6 months. [FL2000 § 3123.]
 - 4.1 All vending machine locations have been inspected every 6 months, or the LHD follows a reduced frequency of inspection policy meeting following requirements: [FL2000 §§ 3123 and 3125.]
 - (a) A written reduced frequency of inspection policy is established and implemented. [FL2000 \S 3125(1).]
 - (b) The policy contains a mechanism for reinstating § 3123 inspection frequency if there are adverse food service sanitation practices within a food service establishment. [FL2000 §§ 3123 and 3125(1).]

- (c) The policy contains a mechanism for reinstating § 3123 inspection frequency if an establishment is implicated in a foodborne illness outbreak. [FL2000 §§ 3123 and 3125(2).]
- (d) A LHD may not reduce inspection frequency to less than one inspection per operator every year. [FL2000 § 3125(3).]
- (e) The frequency of inspection and selection of locations by the LHD assure the widest coverage of each operator's locations over time.

Official Comment

- 1. A LHD policy and procedure for reducing the frequency of inspections of vending locations that was reviewed and approved by MDA under the 2000-01 MPRs would be approved under the 2001-02 changes in Indicator 4.1. An example of such an approved procedure would be one that complied with indicator 4.1(a)-(e), the inspections are made using a random selection method which ensures the widest coverage each operator's locations over time, one inspection is made of each operator every year, and all vending machines are inspected at least once every three years. Another example of such an approved procedure would be one that complied with indicator 4.1(a)-(e), the inspections are made using a random selection method which ensures the widest coverage each operator's locations over time, one inspection is made of each operator every six months, and all vending machines are inspected at least once every five years.
- 2. "Widest coverage" of inspections over time means a LHD may not inspect all vending locations in a two-week period and then cease all further inspections for 3 years. The requirement that vending machine locations be inspected to assure the widest coverage over time was a requirement in the U.S. FDA 1978 Vending Machine Ordinance, which was adopted as part of Michigan's food service law in 1981. This provision was eliminated as a requirement upon adoption of the Food Law of 2000, however, providing widest coverage over time is an important safeguard when inspection frequency is reduced.
- 3. A LHD will not be debited under MPR 4 for improper implementation of a reduced frequency of inspection policy (but rather MPR 9). However, when a reduced frequency of inspection policy is incorrectly implemented, this may result in a failure to complete required inspections.
- **MPR 5** A local health department shall review all food service establishment license applications, and forward its recommendations concerning licensure to the MDA. [FL2000 §§ 3115, 3119(6), 3121, and 3123.]
 - 5.1 The LHD records contain copies of the current license applications indicating the local health department's recommendations concerning licensure. [FL2000 §§ 3115, 3119(6), 3121, and 3123.]

Official Comment

Documentation is required to demonstrate that each establishment's sanitation status has been assessed by a routine inspection conducted within six (6) months of the application approval date or in the case of reduced frequency or seasonal establishments, within the one-year inspection cycle. MDA evaluates Indicator 5.1 by examining an MDA-selected sample of LHD files.

- **MPR 6** A local health department shall inspect all temporary food service establishments, for which required notifications are made to the local health department, and upon compliance, shall issue the temporary license. [FL2000 §§ 3115 and 4125(1).]
 - 6.1 Licensed temporary food service establishments have been inspected. [FL2000 §§ 3115(2) and 4125(1).]
 - 6.2 Temporary food establishment licenses and applications are complete and accurate, which includes inspector signature and date when the facility was inspected. [FL2000 § 3115.]

- 1. On evaluation, MDA will debit a LHD for Indicator 6.1 if less than 98% of the temporary food service establishments licensed have been inspected. Indicator 6.1 is evaluated to a closer tolerance level than Indicator 3.1 because 6.1 deals with temporary food establishments, while 3.1 deals with fixed food establishments. Since food establishment licenses shall not be issued prior to inspection, there is scarce reason for the number of temporary food establishment inspections not to correlate with the number of licenses.
- 2. On evaluation, MDA will debit a LHD for Indicator 6.2 if less than 95% of the temporary food service establishment licenses and applications are complete and accurate. This indicator was added in 2002 because some LHDs have been found with a high percentage of temporary food establishment licenses issued without an inspector's signature or without the date the facility was inspected.

- MPR 7 The program regulatory staff are trained with the skills and knowledge to: a) during inspections, identify critical items (risk factors) that may contribute to foodborne illness; b) correctly interpret and apply regulatory requirements; c) communicate public health principles; d) promote and assist in development of risk control plans; and e) enforce the provisions of the laws. [FL2000 § 2119(2)(b).]
 - 7.1 Within 12 months of employment or assignment to the retail food program, the regulatory staff conducting inspections of food service establishments satisfactorily complete training in the following areas: a) Public health principles; b) Communication skills; c) Microbiology; d) Epidemiology; e) Statutes, regulations, policy; and f) HACCP. [FL2000 § 2119(2)(b).]
 - 7.2 Within 12 months of employment or assignment to the retail food program, the regulatory staff conducting inspections of food service establishments satisfactorily complete field training that includes the following components:
 - (a) Twenty-five joint training inspections with a standardized trainer from a local health department; and
 - (b) Twenty-five independent inspections reviewed by the standardized trainer (either on-site or paperwork review).
 - 7.3 Within 12 months of employment or assignment to the retail food program, the regulatory staff conducting inspections of food service establishments satisfactorily complete five evaluation inspections with a standardized trainer from a local health department or MDA.

Official Comment:

- 1. The MDA Training Program for the Professional Food Service Sanitarian (available on the MDA web site at http://www.mda.state.mi.us/food/sanitarian/training/MDA_Training.htm) and other MDA or FDA courses can provide acceptable training for the components specified in 7.1. Satisfactory completion of each training component should be documented in the individual's training plan. (See www.fda.gov for an example of a training plan.)
- 2. Indicators 7.2 and 7.3 apply to employees hired or assigned to the retail food program after October 1, 2000.
- 3. The local health department food program management in consultation with the standardized trainer have the responsibility for assessing the competency of each staff member. Only those individuals who are judged competent should be allowed to perform independently. Over the 12-month inspection-training period, it is anticipated that the standardized trainer will teach inspection techniques and procedures beginning with simple operations and advance step-by-step toward risk-based inspection methodology at complex full-service establishments. A record should be kept to indicate the date at which each individual is judged to be competent in inspecting vending machines, temporary food establishments, mobile food establishments, special transitory food units, simple/fast food service establishments, and complex food service establishments.
- 4. To demonstrate compliance with MPR 7, the LHD will need to provide documentation of (a) the program, and (b) records of staff completion of each required component.

MPR 8 [Reserved]

MPR 9 The local health department food service inspection program correctly and uniformly interprets and applies the requirements of the Food Law of 2000 and other related laws. [FL2000 §§ 3105, 3109, and 3121.]

Licensing

9.1 If license limitations are issued, they are issued and documented in compliance with the law. [FL2000 §§ 2121 and 2123.]

- 9.2 All food service establishments are inspected prior to licensing. [FL2000 §§ 3115(2) and 4125(1).]
- 9.3 Licensing under the Food Law of 2000 is being correctly and uniformly conducted. [FL2000 §§ 3105 and 3109.]

Inspections

- 9.4 A copy of the completed inspection report, which includes a notice to correct violations, is provided to the person in charge at the completion of the inspection. [FL2000 § 3127.]
- 9.5 The local health department maintains copies of all inspection reports, recommended regulatory actions, and disposition of regulatory actions for the past 60 months. [FL2000 § 3121(4).]
- 9.6 Inspections are conducted in compliance with the Michigan Food Law of 2000. [FL2000 § 3121.]

 Administration
- 9.7 If variances are issued, they are granted in accordance with FC §§ 8-103.10 to 8-103.12 and documented in accordance with FC § 8-103.11. [FL2000 § 6101.]
- 9.8 If there is a reduced inspection frequency policy in use, it is being carried out in accordance with the MDA-approved plan. [FL2000 § 3125.]
- 9.9 The LHD has a written enforcement procedure consistent with the Food Law of 2000. [FL2000 § 3117.]
- 9.10 The local health department justly applies the remedies according to the Food Law of 2000 and other law consistent with the licensee's right to due process. [FL2000 § 5113.]

Official Comment:

- 1. The date of inspection indicated on the application form should be supported by documentation of a routine inspection report in the establishment folder (or equivalent computerized system).
- 2. The dates of operation for all seasonal facilities are complete and accurate on the license applications.
- 3. The record retention requirements are a minimum. A local health department may choose a longer retention cycle if they wish.
- 4. The Indicators under MPR 9 are verified by both field and office review.
- 5. Indicator 9.10 is new to the 2002 MPRs, and it reflects a new provision in the Food Law of 2000, § 5113, which was expressly added by the legislature to address concerns that establishment operators were being denied their constitutional right to due process. In addition, MDA evaluations of LHDs have revealed a number of situations where LHD's policy or standard practice denied, revoked, or suspended food establishment licenses without the opportunity for a hearing. A policy of denying of due process during licensing is the most likely reason a LHD would be debited for this indicator, however, MDA has also encountered sporadic violations regarding administrative fines, such as a policy of not refunding fines when a LHD determined it was incorrect in assessing a fine.
- 6. As used in MPR 9, "correctly and uniformly" means that the LHD policy and standard practices for administration of the Food Law of 2000 are in accordance with the law.
- 7. Establishment of a reduced frequency of inspection policy is a voluntary option of a LHD. However, once elected, this option brings with the responsibility to properly implement the program according to the law and the LHD written policy.

MPR 10 A local health department shall maintain a record of all consumer complaints, the ensuing investigation, and the result of the investigation. [FL2000 §§ 2101(2), 3121(3), 3129, and 3131.]

- 10.1 All consumer complaints pertaining to the food service sanitation program reported to the local health department indicate the results of the required investigation (or justification for not investigating). At the conclusion of the investigation, the findings are recorded in a complaint log or database, and the investigation reports are filed in the establishment record. [FL2000 §§ 2101(2), 3121(3), 3129, and 3131.]
- 10.2 Consumer complaint investigations are completed in a timely manner. [FL2000 §§ 2101(2),

3121(3), 3129, and 3131.]

Official Comment:

- 1. MDA will examine a representative sample of all consumer complaints selected from the local health department's consumer complaint logbook/tracking mechanism to verify that complaints are assessed and investigated, and follow-up activity is documented.
- 2. "Timely manner" for consumer complaint investigation completion generally means within 5 working days.
- 3. "Findings," as used in Indicator 10.1, means a brief notation that explains the results and conclusions of the investigation.
- 4. A food complaint log is required because it is a fundamental component of a foodborne illness surveillance system. The log permits observation of patterns in otherwise isolated complaints. Without a log, many disease outbreaks will go undetected. It is recommended that the log be reviewed each time an entry is made, and also each week to discover clusters of cases or involvement of a common food or place of eating, which might otherwise go undetected. If your agency has district offices, you should periodically send copies of the log sheets (or equivalent) to a central coordinating office. Reference: Food Law 2000, section 3131(2), and "Procedures to Investigate Foodborne Illness, Fifth Edition," published by the International Association of Food Protection.
- **MPR 11** A local health department shall conduct an investigation of foodborne illness and suspected foodborne illness connected with food service establishments and report the findings to MDA in a timely manner. [FL2000 §§ 2101(2), 3121(3), 3129, and 3131.]
 - 11.1 An investigation is initiated within 24 hours of communication of each complaint involving suspected foodborne illness or injury. [FL2000 §§ 3129 and 3131.]
 - 11.2 The number of food-related complaints received and the number of foodborne illness investigations conducted by the LHD is reported quarterly to MDA (the quarterly report). [FL2000 §§ 3129 and 3131.]
 - 11.3 A written, final investigation report has been prepared for each foodborne illness outbreak and a copy sent to the MDA. Reports shall be submitted in a timely manner. [FL2000 §§ 3121(3), 3129 and 3131.]

- When epidemiological analysis supports the decision, and it is documented in the investigation report, the
 complaint investigation may be closed after an interview with the complainant, but without inspection of
 the establishment.
- 2. MDA requests submission of a copy of food-related complaints and foodborne illness investigation reports be submitted to the MDA Food Safety Planning and Response Section on a weekly basis.
- MPR 12 The food service program has an established operating procedure for conducting and communicating foodborne illness outbreak investigations with applicable governmental agencies and organizations. [FL2000 § 3131.]
 - 12. 1 The food service program has developed and implemented an operating procedure for conducting and communicating foodborne illness outbreak investigations with applicable governmental agencies and organizations. This operating procedure is reviewed annually and updated as needed. [FL2000 § 3131(1).]
 - 12.2 This document: (a) describes the foodborne illness outbreak investigation team, (b) defines their roles and responsibilities, and (c) establishes a system for communicating foodborne illness information with LHD employees and other agencies and organizations. [FL2000 § 3131(1).]

- During foodborne illness outbreak investigations, procedures equivalent to the "Procedures to Investigate a Foodborne Illness"5th Ed., published by the International Association of Food Protection are used and documented. [FL2000 § 3131(2).]
- **MPR 13** The inspection process: a) identifies all uncontrolled hazards; b) obtains corrective action on uncontrolled hazards as appropriate; and c) supports appropriate regulatory action. [FL2000 §§ 2119(2), 3121, and 6101; FC § 8-403.10.]
 - 13.1 The LHD's regulatory inspections identify non-conformance with critical items. [FC § 8-403.10(B).]
 - 13.2 The LHD's regulatory inspections document on the inspection report non-conformance with critical items and other specific factual observations of violative conditions of the Food Law that require correction. [FC § 8-403.10.]
 - The LHD's regulatory inspections either achieve corrective action, as appropriate, or support appropriate regulatory follow-up. [FC §§ 8-403.10, 8-403.20, 8-405.11, and 8-405.20; FL2000 §§ 2119(2) and 6101.]

Official Comment:

The primary method MDA uses to evaluate MPR 13 is through an MDA field evaluation of a representative sample of food service establishments to determine the local health department's program uniformity in meeting Indicators 13.1 to 13.2. The LHD inspections must be conducted in accordance with state law; and staff who conduct inspections should focus on identification of uncontrolled hazards, provide proper documentation of this information, communicate critical information to the person in charge, and there should be a management policy of appropriate regulatory follow-up that staff are expected to follow.

- MPR 14 A follow-up inspection shall be conducted by the local health department to confirm correction of all previously identified critical violations, unless the critical violation was corrected at the time of initial inspection. [FL2000 §§ 3105, 3127, 6101 and 6129.]
 - Follow-up inspections have been conducted, preferably within 10 calendar days, but no later than 30 calendar days, of all establishments with uncorrected critical violations during the routine inspections. [FL2000 § 6101, FC § 8-405.11 and 6129.]
 - After observing at the time of inspection a correction of a critical violation, the LHD enters the violation and information about the corrective action on the inspection report. [FL2000 §§ 3127; 6101, FC § 8-405.20; and 6129.]
 - 14.3 Follow-up inspections confirm the correction of critical items in violation, or the LHD has initiated enforcement procedures. [FL2000 §§ 3105 and 6129(2).]

- 1. MDA will pick a representative sampling of establishment records.
- 2. Indicator 14.1 specifies the time frame for a LHD to reinspect for critical violations, which should not be confused with the license holder's time frame for correction. A license holder shall correct critical violations at the time of inspection, however the LHD may specify a longer time frame, not to exceed 10 calendar days after the inspection, for the license holder to correct critical violations.
- 3. Demonstration of compliance with 14.3 requires documentation of the specific violation and corrective action.
- 4. An Indicator under MPR 14 will be found not met if in the MDA sample selected proper follow-up occurred less than 80 percent of the time required.
- 5. Documentation needed to demonstrate compliance with 14.3 includes notation of the specific critical violation and the manner or means of correction.

- **MPR 15** The local health department shall conduct administrative and judicial enforcement actions as required to ensure compliance with statutory and administrative rule requirements. [FL2000 §§ 2101, 3105, and 3109.]
 - 15.1 The local health department has evidence indicating the expedient initiation of enforcement action against all licensed food service establishments that continue to exhibit critical violations after follow-up inspections. Enforcement action should be initiated no later than 14 days after all efforts at voluntary compliance are exhausted, or immediately if an imminent public health hazard exists. [FL2000 §§ 2101, 3105, and 3109.]

Official Comment:

1. MPR 15 will be found not met if in the MDA sample selected compliance and enforcement action occurred less than 80 percent of the time required.

Important Factors

Important Factors are <u>not</u> part of the MPRs.

IMPORTANT FACTOR I -- Educational Outreach

A local health department provides educational opportunities to licensed food service operators in conjunction with the provision of inspection services, or at other times determined by the local health department.

16.1 The local health department provides documentation or demonstration of materials, education seminars, meetings, or training provided.

Official Comment:

Outreach may include industry recognition programs, web sites, newsletters, FightBACtm campaigns, food safety month activities, food worker training, school-based activities, or other activities that increase the awareness of the risk factors and control methods to prevent foodborne illness. Agency participation in at least one activity is sufficient to meet this factor.

IMPORTANT FACTOR II - HACCP Program

The local health department has a food safety program for promoting and implementing HACCP that has been reviewed and approved in advance by MDA.

- 17.1 The local health department has staff that are trained and competent in the HACCP food safety system. MDA staff will conduct a field audit to determine the ability of local health department staff assigned to the HACCP program component to: a) Identify Hazards; b) Determine Critical Control Points, c) Establish Critical Limits, d) Develop Monitoring Programs, e) Prepare Corrective Action Plans, f) Develop Record Keeping Systems, and g) Establish Verification Systems.
- 17.2 The local health department has a strategy and timetable for promoting and implementing HACCP in food service establishments. The plan has been submitted to, and approved by, MDA.
- 17.3 The local health department has a program to recognize food service operators that have demonstrated knowledge and consistent application of the HACCP food safety system.

Official Comment:

- All components of Important Factor II must be satisfied for a LHD HACCP program to be recognized as
 a Factor II HACCP program.
- "HACCP" means the formal procedures for following the Hazard Analysis Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods. See FOOD CODE, Annex 5, 379-412 (FDA, 1999).

IMPORTANT FACTOR III – Continuing Education of Regulatory Staff

- 18.1 A regulatory staff conducting inspections of food service establishments satisfactorily completes at least 16 contact hours of continuing education every 24 months.
- 18.2 A regulatory staff conducting inspections of food service establishments satisfactorily participates in 2 joint inspections with the standardized trainer every 24 months.

Official Comment:

- 1. The continuing education must be in the area of food safety or the six categories listed in Indicator 7.1. Attendance at regional seminars, technical conferences, college courses, workshops, and food-related training provided by government agencies qualify. The local health department may, within reason, qualify education and training as eligible, and may include in-service training.
- 2. Factor 18.2 is set at ½ the recommended requirement in FDA'S RECOMMENDED NATIONAL RETAIL FOOD PROGRAM STANDARDS (2001).

IMPORTANT FACTOR IV -- Inspection Frequency

Not less than 90% of quantity of licensed establishments shall have been inspected at the required frequency.

19.1 Not less than 90% of the required quantity of inspections of licensed establishments have been completed.

Official Comment:

Indicator 19.1 is evaluated with the same methodology applied for Indicator 3.1.

IMPORTANT FACTOR V – Program Support and Resources

Budget, staff, and equipment are available to support an inspection program that is designed and managed to reduce the risk factors known to contribute to foodborne illness and other factors that may contribute to foodborne illness.

20.1 The program budget provides the necessary resources to develop and maintain a food safety program that meets the following: A staffing level of one full-time equivalent (FTE) staff devoted to food for every 125 to 225 establishments. The documentation needed for this standard is the regulatory staff-to-establishment ratio based on full time equivalent (FTE) employees and inspection frequency.

Official Comment:

Important Factor V is derived from the U.S. Food and Drug Administration Standard No. 8, Program Support and Resources (FDA'S RECOMMENDED NATIONAL RETAIL FOOD PROGRAM STANDARDS (2001)). FDA Standard No. 8 requires a staffing level of one full-time equivalent (FTE) devoted to food for every 280-320 inspections performed. The FDA FOOD CODE (1999) recommends that approximately 8 to 10 hours be allocated per establishment per year (approximately 1 FTE allocated for every 125 to 225 food service establishments). This includes time for inspection, follow-ups inspections, complaint investigations, and administrative work, such as plan review, enforcement documentation, hearings, and court actions. The suggested time is based upon a typical mix of establishments and average travel times. See FOOD CODE 339 (FDA, 1999). When an FTE is divided between program areas, the total number of food inspections planned for that FTE should be adjusted to compensate for the additional training time required to maintain competency in multiple program areas. An adjustment in planned inspections per FTE should also occur when food establishments are geographically dispersed.

IMPORTANT FACTOR VI – Industry and Community Relations

An advisory mechanism exists to provide recommendations and consultation to the regulatory program from interested parties.

21.1 There is least an annual meeting of those involved in the advisory mechanism where program support or other food safety issues may be addressed. This advisory mechanism may use a formal

or an informal process, e.g., town meetings, or a formal advisory committee. The recommendations and consultations to the interested parties are documented.

Official Comment:

The purpose of this standard is for the regulatory program to solicit a broad spectrum of input into the food program. The desired outcome is enhanced communication with industry and consumers and is designed to improve the food safety program. Important Factor VI duplicates verbatim portions of the U.S. Food and Drug Administration Standard No. 8, Program Support and Resources (FDA'S RECOMMENDED NATIONAL RETAIL FOOD PROGRAM STANDARDS (2000).

IMPORTANT FACTOR VII - Uniform Inspection Quality Assurance Program

The local health department program management has established a quality assurance program to ensure uniformity among regulatory staff in the interpretation and application of regulatory requirements, policies, and procedures. The quality assurance program includes as a minimum, a record review of both routine inspections and foodborne illness investigations. [FL2000 §§ 2119, 3103, 3105, and 3109.]

- 22.1 The program has a written procedure that describes the jurisdiction's quality assurance program. The quality assurance program is: (a) ongoing, (b) describes the actions that will be implemented if the review identifies deficiencies in quality or consistency, and (c) assures that inspection staff:
 - a) Reports are accurate and complete (identify and document non-conformance with critical items and other factual observations of violative conditions of the Food Law of 2000 that require correction):
 - b) Regulatory requirements are interpreted properly;
 - c) Current inspections accurately correlate to follow-up requirements from previous inspections (action is taken on repeated or unresolved violations);
 - d) Complete explanation of violations (cite or describe the proper law and code provisions);
 - e) Obtain and document on-site corrective actions by establishment management at the time of inspection as appropriate to the violation;
 - f) Appropriate regulatory actions are recommended and documented; and
 - g) Variance information is documented in the records (establishment file).
- 22.2 The review by the LHD's quality assurance program demonstrates an acceptable uniformity level. If the review reveals an unacceptable level of uniformity, a plan of action is developed by local health department management to address the need for uniformity among regulatory staff.
- 22.3 Documentation is maintained of a record review for each staff member.

- 1. Prior to October 1, 2002, Important Factor VII was substantially contained in MPR 8 (the requirement of specific quantities of paperwork reviewed was eliminated when transferred from MPR 8).
- 2. For recommendations on establishing internal policy and procedures to ensure uniformity, refer to FDA Standard No. 4 in FDA'S RECOMMENDED NATIONAL RETAIL FOOD PROGRAM STANDARDS (2001), which is available at www. fda.gov. It is recommended that the procedure result in a minimum of a review at least every 24 months of a representative sample of 5 full days of each inspector's food inspection records.

Evaluation

Evaluation as "met" and "not met"

Minimum Program Requirements (MPRs) are evaluated as "met" and "not met."

Review period under evaluation

The standard evaluation review period is the three previous years. Occasionally, a shorter review period may be specified in an indicator. On other occasions, a longer review period may be necessary; for example, when a longer period is necessary to provide sufficient records.

Documentation

A local health department is expected to produce documentation to demonstrate compliance with each requirement. Absent records are evaluated as being non-existent for review purposes, regardless of the reason for the absence. For example, absent inspection reports cannot be counted as completed inspections.

Example: on evaluation of MPR 7 on training, a local health department is expected to provide the documents supporting the training program, such as policy and procedures and records of staff completion of the required components.

Example: on evaluation of MPR 1 on plan review, a local health department will be expected to produce the required records of plans review and associated correspondence for new construction, conversions, and remodeling.

Corrective Plan of Action

A corrective plan of action (CPA) is expected from a local health department for each MPR Indicator that has been found not met during MDA's evaluation. The Accreditation Program procedure requires original corrective plan of actions be submitted to the accreditation administrative staff. To expedite review and acceptance by MDA, local health departments should send a copy directly to MDA as soon as the proposed corrective plan is completed.

Deadline for Submission

The Accreditation Program Protocols and Policies (2002) states, "Local health departments must submit corrective plans of action to the Accreditation Program within 2 months of their on-site review (e.g., if on-site review begins August 4th, the CPA would be due October 4th)." For more information on the Accreditation Program Protocols and Policies, see http://www.accreditation.localhealth.net/.

We encourage local health departments to submit their corrective plan of actions as soon as possible after evaluation. MDA may require earlier submission when the public health and welfare or other exigent circumstances necessitates faster response.

Content

The corrective plan of action must address in writing a specific plan that includes:

- 1) The specific steps taken or to be taken to correct all of the deficiencies in each Indicator noted during the evaluation;
- 2) Each step the agency is taking to prevent the recurrence of similar deficiencies; and
- 3) New policies and procedures where appropriate.

Follow-up Review

Within one year of MDA acceptance of the corrective plan of action, the LHD is expected to request a follow-up review by MDA evaluators to demonstrate compliance with the previously unmet Indicators. Upon re-evaluation, the LHD must demonstrate a minimum of three months of compliance with the corrective plan of action for the Indicator to be found met.

Temporary Waiver & Mootness

Temporary Waiver from an Indicator

MDA may grant a temporary waiver from an indicator if, in MDA's opinion, all of the following conditions are met:

- 1. Acceptable alternative practices are in place;
- 2. The variance is not detrimental to the overall requirement of the MPR;
- 3. The alternative practices would not violate the law;
- 4. Compliance with the indicator would create a practical hardship on the LHD; and
- 5. The local health department's situation is unique.

Requests for a waiver must be in writing to the manager of the food service sanitation section and include documentation of all five of the above conditions being satisfied. In some cases, a complete program self-assessment may be needed to support the request.

A request for a waiver must be received by MDA before a local health department starts the accreditation self-assessment period. No request for a waiver will be considered during MDA field evaluation.

Application of the Mootness Principle on Evaluation of LHDs

This policy is to clarify when the MDA Evaluation Officer may apply the principle of mootness to a local health department's (LHD) failure to meet a Minimum Program Requirement (MPR).

THE PRINCIPLE

The mootness principle applies to a deficiency that has been completely resolved, and there is <u>no</u> likelihood that the deficiency will recur. When an evaluation reveals an MPR Indicator has been unmet during the review period, but the LHD complies with the requirement on the date of the evaluation, the Evaluation Officer may examine the deviation under the principle of mootness. Before applying the mootness principle, the standard of proof is a heavy one. The LHD must demonstrate that it is *absolutely clear* that the deficiency could not reasonably be expected to recur.

PROCEDURE

All four of the following elements must be met during the evaluation before the mootness principle may be applied to a LHD evaluation:

1) The deficiency has clearly been *completely* corrected (or the Indicator has ceased to exist). Predictable protestations of repentance and reform are insufficient and must be supported with factual evidence of

complete correction.

- 2) The facts demonstrate that it is *absolutely clear the deficiency could not reasonably be expected to recur*. A good or a lucky day is not a state of compliance. Nor is a dubious state in which a past problem is not recurring at the moment, but the cause of the problem has not been completely eradicated. Thus, a deficiency found deficient on two consecutive evaluations is virtually always precluded under this element from being moot on the latest evaluation.
- 3) Elements 1 and 2 above are *documented* in the evaluation report before the mootness principle may be applied.
- 4) To ensure consistency, all use of the mootness principle must be reviewed and approved by the Evaluation Officer prior to application.

Glossary

- "Accreditation" means accreditation by the Michigan Local Public Health Accreditation Program.
- "Critical Violation" means a provision of the law that, if in non-compliance, is more likely than other violations to contribute to food contamination, illness, or environmental health hazards. The law designates certain sections of the Food Code as critical items (see Food Code § 1-201.10(B)(17)). Examples include failure to cool foods properly, failure to cook or reheat foods to proper temperature, improper hot/cold holding, poor hygienic practices, cross-contamination, unapproved food source, inadequate sanitation procedures, and failure of equipment to maintain potentially hazardous food at proper temperatures.
- "FDA" means the United States Public Health Service Food and Drug Administration.
- **"Food Code"** means the Food Code (FDA, 1999) that regulates the design, construction, management, and operation of certain food establishments and is adopted by reference in the Food Law of 2000, § 6101.
- **"Foodborne illness outbreak"** means an incident where two or more persons, not of the same household, have ingested a common food and have a similar disease, similar symptoms, or excrete the same pathogens, and there is a time, place, or person association between these persons; where there is a single case of suspected botulism, mushroom poisoning, paralytic shellfish poisoning, or other rare disease; or where there is a case of a disease or poisoning that can be definitely related to ingestion of a food.
- "FL 2000" means the Michigan Food Law of 2000, Public Act No. 92 of 2000, being MCL 289.1101 et seq.
- **"LHD"** means a local health department delegated authority and responsibility for the enforcement of the requirements pertaining to food service establishments contained in the Food Law of 2000.
- "MDA" means the Michigan Department of Agriculture.
- "MPR" means Minimum Program Requirement.
- **"Standardization Training"** means a process whereby the trainer provides an individual with the knowledge and skills to correctly interpret and apply the food service sanitation requirements.
- **"Standardized Trainer"** means a trainer certified by MDA as possessing the knowledge and skills to correctly interpret and apply the food service sanitation requirements.
- **"Suspected Foodborne Illness"** means an unconfirmed association of an illness with a food, such as a consumer complaint.
- **"Uncontrolled hazard"** means a biological, chemical, or physical property that may cause an unacceptable consumer health risk if left uncontrolled. Uncontrolled hazards include both critical violations and non-critical violations that may, if left uncontrolled, increase the risk of foodborne illness. For example, under the 1997 Food Code, water temperature at a handwashing sink is a non-critical violation; however, if the water is so cold that employees do not wash their hands before handling ready-to-eat food, then the violation increases the risk of foodborne illness.
- "Uniformity" means the degree an inspector's documents and records match the standard for accuracy, application of law and policy, etc.

APPENDIX A

Recommended Change Form

The following changes are recommended to the Minimum Program Requirements For Food Service Sanitation Regulatory Programs document administered by the Food Service Sanitation Section of the Michigan Department of Agriculture:

CONCERN:
SPECIFIC SECTION OF DOCUMENT FOR CHANGE:
EXPLAIN WHAT THE CURRENT SECTION DOES NOT ACCOMPLISH AND WHY THE LANGUAGE SHOULD BE CHANGED:
RECOMMENDED LANGUAGE FOR CONSIDERATION:
Name of submitter: Date:

Return to: Manager, Food Service Sanitation Section, MDA, P.O. Box 30017, Lansing, MI 48909